WRAIR #1856: A Phase 1 Trial of the WRAIR Dengue Serotype-1 Purified Inactivated Virus Vaccine (DEN-1 PIV) in Flavivirus Antibody Naïve Adults

- HRPO log # A-16341, IND number 14464-0000
- PI: LTC Thomas

Information below is taken directly from protocol v3 (21 NOV 2011)

Study Name:

"A Phase 1 Trial of the Walter Reed Army Institute of Research (WRAIR) Dengue Virus Serotype-1 Purified Inactivated Vaccine (DENV-1 PIV) in Flavivirus Antibody Naïve Adults".

Background:

This study involves an experimental dengue vaccine. Dengue is a common infection affecting travelers to many areas of the world, including Southeast Asia, Central America, South America and the Caribbean. It is caused by a virus and is transmitted by a mosquito. Dengue can cause fever, tiredness and even severe bleeding or death. It can pose a threat to military operations, and because of this, the military is trying to develop a vaccine to protect against dengue.

This study involves an experimental dengue vaccine. This is the first time that this dengue vaccine will be used in humans. It will take place at a clinic-type facility in Silver Spring, Maryland. The vaccine will be given in your shoulder using a needle and blood samples will be collected to look at your body's response. The goals of this study are to determine if the vaccine is safe and how your body responds to the vaccine.

Duration:

This study will last about 200 days including the time involved for screening. One or two clinic visits are required to see if you qualify for the study. If you are accepted into the study, you will receive 2 doses of vaccine. After each injection, there will be follow-up visits. There will be a total of 10 scheduled clinic visits (not including the initial screening) and 2 telephone call sessions.

Requirements and Restrictions:

You must meet certain requirements to participate in this study, which I am going to list for you. You don't have to respond, but you may ask questions if you want me to clarify any of the following requirements or restrictions:

1. Volunteers must be at least 18 and not older than 50.
2. Volunteers must be in good health and have no significant current or past diseases.

1. Volunteers must not have had an infection or been vaccinated against Japanese Encephalitis, Yellow Fever, West Nile, or dengue virus.
2. Active duty military members need a signed approval memo from their supervisor to participate.
3. Volunteers must have access to the Naval Medical Research Center and Walter Reed Army Institute of Research (WRAIR) in Silver Spring, be willing to attend all of the required visits over approximately 200 days (including screening), and be willing to refrain from participation in any other clinical studies involving investigational drugs or vaccines while participating in this study.

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4. Volunteers must agree to not become pregnant or breastfeed during the study and also be willing to use a reliable form of contraception during the study
5. Volunteers must not have donated or received blood, blood products, or plasma within 90 days prior to starting the study or plan on donating blood or plasma during the study.
8. Volunteers cannot participate if they plan to travel to an area where dengue is common during the study period.

There may be other reasons why you cannot participate in this study and those will be discussed at the screening visit.

Possible Risks

There are risks associated with receiving this vaccine. This is the first time this dengue vaccine will be given to humans. Parts of the vaccine have been given to animals, and the Food and Drug Administration, or FDA, has approved the use of this vaccine for this study.

We will start with a low dose of the vaccine in the first group of volunteers and then increase to a higher dose in a second group of volunteers if the low dose is safe.

Based on experience with similar vaccines, mild reactions are expected. These generally include tenderness, redness and swelling at the injection site. These reactions will most likely resolve on their own within a few days. You may also experience other reactions, such as headache, a low fever, or flu-like symptoms. There may be some risks that are unknown.

After each vaccination you will see a physician in the clinic who will evaluate the number and type of reactions.

Compensation

You will receive compensation for participating in this study. Civilians or off-duty military will be compensated a maximum of $1025:

- $25 for screening visit (1 total)
- $100 for visit with a blood draw (10 total)
- $25 for referring another volunteer into the study (Referral Bonus)

On-duty military personnel and federal employees will be compensated a maximum of $525 :

- $25 for screening visit (1 total)
- $50 for visit with a blood draw (10 total)

Federal employees will be compensated at the same rate as active duty military subjects (in accordance with the Dual Compensation Act). Both active duty military and federal employees are not eligible for off-duty compensation unless on approved leave, or unless a visit occurs outside of normal duty hours. Volunteers will not be compensated for unscheduled visits.